UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

ALZHEIMER'S INSTITUTE OF AMERICA, INC.,)))	
Plaintiff,)	
v.)	Civil Action No. 4:09-cv-01026 (CAS)
PFIZER INC.,)	JURY TRIAL DEMANDED
Defendant.)	

DEFENDANT PFIZER INC.'S ANSWER AND COUNTERCLAIMS

Defendant, Pfizer Inc. ("Pfizer"), for its Answer to the Complaint ("the Complaint") of Plaintiff, Alzheimer's Institute of America, Inc. ("AIA") and Counterclaims, states:

NATURE OF THE ACTION

1. Pfizer admits that Exhibits A, B, and C to the Complaint purport to be true and correct copies of U.S. Patent Nos. 5,455,169 (the '169 patent), 5,795,963 (the '963 patent), and 6,818,448 (the '448 patent) (collectively, the "patents-in-suit"). Except as so admitted, Pfizer denies the allegations in this paragraph.

JURISDICTION AND VENUE

2. Pfizer admits that AIA's Complaint purports to state a cause of action under the Patent laws, 35 U.S.C. § 1 *et seq.* Pfizer admits this Court has subject matter jurisdiction over such a cause of action under 28 U.S.C. §§ 1331 and 1338(a).

3. Pfizer admits that it transacts business in this district, but states that its business does not infringe any valid claim of any of the patents-in-suit, either directly or indirectly. Pfizer further states that even if venue is proper in this district, it is inconvenient.

THE PARTIES

- 4. Pfizer lacks sufficient information to form a belief as to the truth of the allegations of this paragraph, and so denies such allegations.
- 5. Pfizer admits that it is a corporation organized and existing under the laws of Delaware with corporate headquarters at 235 East 42nd Street, New York, NY, 10017. Pfizer denies committing any acts of infringement concerning the patents-in-suit or any other tortious or unlawful acts in this District or any other.

FACTS

- 6. Pfizer admits that it (or a predecessor corporation, Pharmacia) engaged in communications with AIA, from about 2000 to 2003, concerning at least the '169 and/or the '963 patents. Pfizer further admits that a communication dated August 21, 2003 identified in the complaint contains the text quoted by plaintiffs. Except as so admitted, Pfizer denies the allegations in this paragraph.
- 7. Pfizer admits that it acquired Rinat Neuroscience Corp. in April of 2006. Except as so admitted, Pfizer denies the allegations in this paragraph.
- 8. Pfizer admits that research on Alzheimer's Disease is one of Pfizer's many projects. Except as so admitted, Pfizer denies the allegations in this paragraph.
- 9. Pfizer admits that it provided funding or support for, or its scientists participated in at least a portion of the research discussed in these five cited publications. Except as so admitted, Pfizer denies the allegations in this paragraph.

COUNT I

Patent Infringement of U.S. Patent No. 5,455,169

- 10. Pfizer incorporates by reference the responses in paragraphs 1-9 above.
- 11. Pfizer admits that the U.S. Patent and Trademark Office issued the '169 patent. Except as so admitted, Pfizer denies the allegations in this paragraph.
 - 12. Pfizer denies the allegations in this paragraph.
 - 13. Pfizer denies the allegations in this paragraph.

COUNT II

Patent Infringement of U.S. Patent No. 5,795,963

- 14. Pfizer incorporates by reference the responses in paragraphs 1-13 above.
- 15. Pfizer admits that the U.S. Patent and Trademark Office issued the '963 patent. Except as so admitted, Pfizer denies the allegations in this paragraph.
 - 16. Pfizer denies the allegations in this paragraph.
 - 17. Pfizer denies the allegations in this paragraph.

COUNT III

Patent Infringement of U.S. Patent No. 6,818,448

- 18. Pfizer incorporates by reference the responses in paragraphs 1-17 above.
- 19. Pfizer admits that the U.S. Patent and Trademark Office issued the '448 patent.
- Except as so admitted, Pfizer denies the allegations in this paragraph.
 - 20. Pfizer denies the allegations in this paragraph.
 - 21. Pfizer denies the allegations in this paragraph.

PRAYER

Pfizer denies each averment in AIA's complaint to the extent not expressly admitted herein and denies that AIA is entitled to any of the relief requested in its prayer for relief, or any relief whatsoever.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

22. Pfizer is not infringing and has not infringed, either directly, contributorily, or by inducement, any valid claim of the '169 patent, the '963 patent, and/or the '448 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

23. Pfizer's allegedly infringing activities are exempt from infringement under 35 U.S.C. § 271(e)(1).

THIRD AFFIRMATIVE DEFENSE

- 24. Pfizer's allegedly infringing activities are immune from any action on infringement by reason of various licenses obtained by Pfizer and/or its predecessor companies.
- Warner-Lambert obtained a license from Mayo Foundation For Medical A. Education And Research ("Mayo") in 1996 for the use of certain technologies relating to the research of Alzheimer's disease. Warner-Lambert was acquired by Pfizer in 2000.
- В. Pharmacia obtained a license from Mayo in 1996 for the use of certain technologies relating to the research concerning Alzheimer's disease. Pharmacia was acquired by Pfizer in 2003.
- C. Pfizer obtained a license from Mayo in 2003 for the use of technologies relating to the research of Alzheimer's disease.

- D. Rinat Neurosciences obtained a license from Mayo in 2005 for the use of technologies relating to the research of Alzheimer's disease. Rinat Neurosciences was acquired by Pfizer in 2006.
- 25. Pfizer's research activities are also non-infringing by reason of various assignments Pfizer obtained from the true and correct co-inventors of the '169 patent, the '963 patent, and/or the '448 patent. These assignments include:
- A. Pharmacia obtained an assignment from Dr. Henry Houlden in 2001 for all his rights, title and interest concerning his work relating to among other things, the Swedish Mutation, including any inventions claimed in the '169 patent, the '963 patent, and any continuation patents, including the '448 patent. Pharmacia was acquired by Pfizer in 2003.
- B. Pharmacia obtained an assignment from Dr. Bengt Winblad, Dr. Lars Lannfelt, and Karolinska Institute in 2001 for all their rights, title and interest concerning their work relating to among other things, the Swedish Mutation, including any inventions claimed in the '169 patent, the '963 patent, and any continuation patents, including the '448 patent. Pharmacia was acquired by Pfizer in 2003.

FOURTH AFFIRMATIVE DEFENSE

26. Each and every claim of the patents-in-suit is invalid for failure to comply with the patent laws 35 U.S.C. § 1 *et seq.*, including, but not limited to 35 U.S.C. §§ 102, 103, 112, and/or 116 (inventorship).

FIFTH AFFIRMATIVE DEFENSE

27. Prosecution history estoppel and/or prosecution disclaimer precludes any finding of infringement.

SIXTH AFFIRMATIVE DEFENSE

- 28. The relief sought by AIA is barred in whole or in part by the doctrine of laches and/or equitable estoppel.
- 29. AIA contacted Pharmacia at least as early as January 19, 2000, asserting that Pharmacia's research activities were infringing AIA's '169 and '963 patents. AIA subsequently sent several letters setting various deadlines for responses from Pharmacia, and including other threats, e.g., letters dated May 5, 2000, August 11, 2000 and February 20, 2003. That conduct and AIA's subsequent conduct gives rise to laches and/or estoppel.

SEVENTH AFFIRMATIVE DEFENSE

- 30. The '169 patent, the '963 patent, and the '448 patent are unenforceable pursuant to the doctrine of inequitable conduct.
- 31. Upon information and belief, Dr. Michael Mullan and/or others owing a duty of candor to the United States Patent and Trademark Office ("USPTO"), committed inequitable conduct during the prosecution of the '169 patent, the '963 patent, and the '448 patent.
- A. While the applications leading to the '169, '963 and '448 patents were pending before the USPTO, Dr. Michael Mullan claimed to be the "sole inventor" of the patents-in-suit, even though he knew that he alone had not initiated or carried out the work to identify the "Swedish Mutation."
- В. Dr. Mullan's assertions to the USPTO claiming to be the "original, first, and sole inventor" of the '169 patent, the '963 patent, and the '448 patent were false and misleading, and on information and belief, were made with an intent to deceive.
- C. Upon information and belief, before or during the period when the applications issuing as the '169, '963 and '448 patents were pending before the USPTO, Drs. Winblad and

Lannfelt challenged Dr. Mullan's assertion that he was the sole inventor of the inventions being claimed in these patents. Dr. Mullan and others with a duty of candor to the USPTO were thus aware of a dispute over inventorship but did not disclose the existence of this dispute to the USPTO.

- D. On information and belief, Dr. Mullan knew, or should have known, that one or more other individuals including, but not limited to, Drs. Hardy, Houlden, Winblad, and/or Lannfelt should have been named as co-inventors of the '169, '963 and '448 patents.
- E. On information and belief, Dr. Mullan knew, or should have known, that representing himself as the "sole inventor" and/or withholding information regarding the inventive contributions of Drs. Hardy, Houlden, Winblad, Lannfelt and/or other individuals from the USPTO was material to the '169, '963 and '448 patents.

EIGHTH AFFIRMATIVE DEFENSE

32. AIA's patent infringement claims are barred, in whole or in part, by the doctrine of unclean hands.

NINTH AFFIRMATIVE DEFENSE

33. Pfizer reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States, and any other defenses, at law or in equity, that may now exist or in the future be available based on discovery and further factual investigation in this case.

TENTH AFFIRMATIVE DEFENSE

34. Plaintiff is not entitled to injunctive relief because Plaintiff has not and will not suffer irreparable harm for which damages would be an inadequate remedy.

COUNTERCLAIMS

Pfizer asserts the following counterclaims against Plaintiff AIA:

NATURE OF THE ACTION

35. Pfizer asserts these counterclaims under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, to obtain a declaratory judgment that each and every claim of U.S. Patent Nos. 5,455,169 (the '169 patent), 5,795,963 (the '963 patent), and 6,818,448 (the '448 patent) is neither valid nor infringed.

JURISDICTION AND VENUE

36. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction over this counterclaim pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

THE PARTIES

- 37. Counterclaim-Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware with Corporate Headquarters at 235 East 42nd Street, New York, NY, 10017.
- 38. On information and belief, Counterclaim-Defendant Alzheimer's Institute of America Inc. is a corporation organized and existing under the laws of Florida with its principal place of business in Kansas.

FACTS

- 39. AIA has alleged that it is the owner of the '169, '963, and '448 patents.
- 40. AIA has expressly charged Pfizer with knowing and willful infringement of the '169, '963, and '448 patents by filing a complaint against Pfizer in this Court [Docket No. 1].

Pfizer denies these allegations. Thus, for at least this reason, there exists an actual controversy between AIA and Pfizer regarding the '169, '963, and '448 patents.

41. AIA asserts that the '169 patent, '963 patent, and/or '448 patent are valid. Because Pfizer contends that each patent is invalid, an actual and justiciable controversy has arisen and now exist between AIA and Pfizer.

COUNT I

Declaratory Judgment of Noninfringement

- 42. Pfizer repeats and incorporates by reference all of the allegations set forth in paragraphs 22-41.
- 43. Pfizer has not been and is not now infringing any claim of the '169 patent, '963 patent, and/or '448 patent, either directly or indirectly.
 - 44. Pfizer's activities are exempt from infringement under 35 U.S.C. § 271(e)(1).

COUNT II

Declaratory Judgment of Invalidity

- 45. Pfizer repeats and incorporates by reference all of the allegations set forth in paragraphs 22-44.
- 46. Each and every claim of the '169 patent, '963 patent, and/or '448 patent is invalid for failure to comply with the patent laws 35 U.S.C. § 1 *et seq.*, including, but not limited to 35 U.S.C. §§ 102-103, 112, and 116.

COUNT III

Declaratory Judgment of Unenforceability

47. Pfizer repeats and incorporates by reference all of the allegations set forth in paragraphs 22-46.

48. Each and every claim of the '169 patent, the '963 patent, and/or the '448 patent is unenforceable pursuant to the doctrine of inequitable conduct.

JURY DEMAND

49. Pfizer demands a trial by jury of all issues so triable in this action.

WHEREFORE, Pfizer Inc. prays for judgment in its favor and against Alzheimer's Institute of America Inc. as follows:

- Dismissing with prejudice AIA's claims against Pfizer; A.
- B. Declaring that Pfizer has not been and is not now infringing any claim of U.S. Patent Nos. 5,455,169 (the '169 patent), 5,795,963 (the '963 patent), and 6,818,448 (the '448 patent);
 - C. Declaring that each and every claim of the '169, '963, and '448 patents is invalid;
 - Declaring that the '169, '963, and '448 patents are unenforceable; D.
- E. Denying AIA's request for damages, costs, attorneys' fees, interest, and injunctive relief;
- F. Declaring this an "exceptional case" under 35 U.S.C. § 285 and awarding Pfizer its expenses, costs, and attorneys' fees; and
- G. Granting Pfizer such other and further equitable or legal relief as the Court deems just and proper.

Dated: August 17, 2009

By: /s/Glenn E. Davis

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CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2009, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system upon the following:

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